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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,011	02/14/2001	Contreras	JAB-1415	1386

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EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JC 3/07/05 RA

Office Action Summary	Application No.	Applicant(s)	
	09/763,011	CONTRERAS,	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/14/2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,22-26,28-35 and 38-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17,22-26,28-35 and 38-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a preliminary amendment, filed 01/25/2002, that inserts sequence identifiers where certain sequences occur in the specification. In addition, receipt is acknowledged of a preliminary amendment, filed 01/14/2001, that cancels claims 18, 19, 20, 21, 27, 36, 37, amends claims 1-7, 9, 11-12, 15, 17, 22-24, 26, 28, 30-35, 38-40, and adds new claims 41-44. Therefore, claims 1-17, 22-26, 28-35 and 38-44 are pending and under consideration in this action.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Each group is designated with an Arabic numeral (*italics*) and groups may be numbered in sets (e.g., 1 to 58), where each group within the set is defined by a particular SEQ ID NO and represents a distinct invention. The groups are as follows:

1 to 58. Claims 1-4, 6-8, 15-17, 35 and 40, drawn to 58 distinct nucleic acid compositions, each of which is represented by SEQ ID NOs recited in claim 1, as well as vectors comprising said sequences.

59 to 108. Claims 5, 6-8, 15-17, 35 and 41, drawn to 50 distinct nucleic acid compositions, each of which is represented by SEQ ID NOs recited in claim 5, as well as expression vectors comprising said sequences.

109 to 216. Claims 9-10, 39 and 43, drawn to 108 antisense molecules (and kits containing the same), each of which is represented by SEQ ID NOs recited in claims 1 and 5.

217 to 323. Claims 11-14, drawn to 108 polypeptide molecules, each of which is encoded by SEQ ID NOs recited in claims 1 and 5.

324 to 430. Claims 22 and 44, drawn to pharmaceutical compositions comprising nucleic acid molecules, each of which is represented by SEQ ID NOs recited in claims 1 and 5.

431 to 537. Claim 22, drawn to pharmaceutical compositions comprising polypeptide molecules, each of which is encoded by sequences represented by SEQ ID NOs recited in claims 1 and 5.

538 to 644. Claim 23 and 24, drawn to *Candida albican* cells comprising a mutation, each mutation in the DNA sequences represented by SEQ ID NOs recited in claims 1 and 5, as well as a method for identifying compounds affecting said cells growth and survival.

645. Claims 25, 26 and 28, drawn to a compound, further a pharmaceutical compound.

646. Claims 32 and 33, drawn to the plasmid pGAL1PsiST-1.

647 to 753. Claims 34 and 39, drawn to antibody molecules (and kits containing the same) raised against proteins, each antibody molecule defined by the protein as encoded by nucleic acid sequences represented by SEQ ID NOs recited in claims 1 and 5.

754. Claims 29-31, drawn to a method for identification of DNA sequences from any cell or organism where the sequences encode proteins critical for that organism, further the organism is yeast, particularly *S. cerevisiae*, *S. pombe* or *C. albicans.*

755. Claim 38, drawn to a method for identification of the presence of *C. albicans* in a subject by examining antibody binding.

756. Claim 38, drawn to a method for identification of the presence of *C. albicans* in a subject by examining nucleic acid hybridization.

The claims encompass 756 distinct inventions. The inventions listed in Groups 1 to 756 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCR Rule 13.2 which indicates that unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features (i.e. technical features that define a contribution which each of the inventions considered as a whole makes over the prior art). More particularly, the groups are directed to sets of inventions where each set is further drawn to distinct compositions, such as nucleic acid molecules, proteins, antibodies, expression vectors, cells and distinct methods.

Therefore, it should be noted at the outset that where the set comprises "like compounds" (e.g., nucleic acid molecules), each invention/group within the set is defined by the particular sequence that is claimed. In other words, each SEQ ID NO represents a special technical feature. For example, groups 1 to 58 comprise 58 distinct nucleic acid molecules each of which is defined by the special technical feature of the particular structure (i.e., sequence) of the compound and the attendant functionality (i.e., encoding a specific protein), thus group 1 would comprise the nucleic acid molecule of SEQ ID NO: 1. It follows, that the proceeding discussion of special technical features will not repeat this distinction as amongst the various sets of inventions, where each set is directed to a composition or method. In sum, within each set of the various composition inventions, each distinct invention is defined by the particular sequence claimed.

The sets of inventions include the following designations: nucleic acid molecules, antisense molecules, polypeptides, expression vectors, pharmaceutical compositions (subset with nucleic acids; subset with polypeptides), cells and antibody molecules. Furthermore, it should be further noted, that where a set comprises 108 different groups, each of the groups from 1 to 58 within the set corresponds sequentially to the SEQ ID NOs as recited in claim 1, thus the remaining groups 59 to 108 correspond sequentially to the sequences as recited in claim 5. Where applicable dependent claims that are more narrowly drawn to a particular SEQ ID NO, would necessarily be drawn to the same invention, since the base claim recite the same SEQ ID NOs (e.g., claims 1 and 4, both recite SEQ ID NOs 1 and 91). For example, if Applicant were to chose the nucleic acid composition of SEQ ID NO 1, then claims 1-4, 6-8 and 40 would be elected and limited to SEQ ID NO: 1. In this hypothetical, all other sequences claimed within the base or dependent claims would be withdrawn as non-elected subject matter.

Generally if there is a unity of invention, the first claimed product, method of making and method of using the claimed product are included as one group. In the instant case, the cells and methods of using the cells (groups 538 to 644; claims 23 and 24) are included as a single invention as the mutated *C. albicans* and methods of using said cells for identification compounds that modulate expression of particular polypeptides. Within this set of cells/methods, there are 108 distinct inventions as defined by the particular sequences that encode particular proteins. For example, one mutated cell is not interchangeable with another to elucidate modulators for the particular mutated sequence, because a compound that modulates one expression profile would not necessarily modulate or affect the expression profile of another gene.

Therefore, each particular sequence that is mutated defines the special technical feature, which in turn identifies a cell as a distinct invention. None of the other sets are directed to the special technical feature of utilizing mutations in particular sequences to screen for expression modulators. Furthermore, no other methods encompass the same steps or elements of the mutated *C. albican* cells, thus do not share this special technical feature.

In the set of nucleic acid compositions, a nucleic acid molecule inheres a distinct special technical feature that is defined by the structure or sequence of the molecule and the correlated function of encoding a protein. Therefore, nucleic acid molecules are directed to distinct special technical features of encoding a particular protein, a feature not shared by any other group/set. The various nucleic acid molecules are not interchangeable or equivalent, because each sequences encodes a distinct protein, thus a distinct functionality.

It follows, that proteins are defined by the particular secondary/tertiary structure, including folding, etc., and the corresponding functionality that is attributable to the protein in the cell. Each protein has a distinct structure and function that defines the special technical feature, where said special technical feature is not shared with nucleic acid molecules, compounds or pharmaceutical compounds. Furthermore, the various proteins encoded by the 108 distinct nucleic acid sequences would each be directed to a specialized function in the cell. Moreover, merely pointing out that all the proteins identified are critical for growth/survival, does not equate to the proteins having a single functionality, thus equating to unity of invention. The specification explicitly indicates that for the sequences recited in claim 5, "no apparent functionality has been assigned", thus further supporting the assertion that each protein defines a special technical feature. (Specification, p. 2, bottom).

For example, if the proteins each functioned in a redundant manner to act as a kinase of the same enzyme (e.g., activating/deactivating enzyme X), then each of the proteins would have an equivalent and redundant functionality, while not necessarily having the same sequence. However, even in such an example, each protein is defined by the structure to functional correlation that defines the special technical feature, thus there would be still be a lack of unity amongst the hypothetical group of proteins all phosphorylating protein X. In the instant set of proteins, teach protein clearly has a distinct structure and the only defined functionality is generic in that it is directed to cell growth/survival, which entails a host of distinct mechanisms/elements in the cell.

With respect to pharmaceutical compositions, a protein or nucleic acid molecule that is to be used as a pharmaceutical composition, because where a composition is defined as "pharmaceutical" that composition is directed to *in vivo* animal or human use, which means that the special technical feature of the protein or whatever composition is contemplated, is wholly different from the composition alone. In other words, the special technical feature for a pharmaceutical protein composition is defined, first by the protein, and second, by the implications for *in vivo* use (e.g., dosage, immune response, toxicity, etc.). It follows, that a pharmaceutical protein compositions inheres a distinct special technical feature as compared to a pharmaceutical nucleic acid composition. For example, the same obstacles and or concerns for a nucleic acid molecule would simply not be present for a protein molecule, or at least would not be interchangeable between the two groups (e.g., transformation, cell entry, genotoxicity versus immunotoxicity, etc.).

With respect to antisense molecules, the special technical feature is hybridization, which is defined by the particular structure of the antisense molecules. Such molecules have been and are considered a wholly distinct compositions, because antisense molecules do no require the same structure (i.e., sequence) to effectuate a wholly distinct functionality. For example, an antisense molecule can hybridize to target molecules, even under relatively stringent conditions, where nucleotide mismatches or lack of complementarity exists. Therefore, the functionality of hybridization is defined by the particular antisense structure, where said structure is not the equivalent of the nucleic acid sense strand that normally encodes a particular protein. Therefore, the set of nucleic acid molecules does not share the same special technical feature as the set of antisense molecules. In addition, no other group is directed to the special technical feature of hybridizing to other nucleic acid molecules.

Each of the molecules in the set of antibody molecules is directed to the special technical feature of binding a distinct protein, thus is distinguishable as against any other antibody based on the protein target, and is distinguishable from any other group based on the functionality of binding other proteins.

With respect to the method for identification of DNA sequences involved in cell or organism's growth/survival, the various steps, elements and components necessary to achieve the outcome of identification define the special technical feature. The steps include preparation of a cDNA library or genomic library, mobilization of said library into a vector, transforming cells and selecting transformants exhibiting impaired growth. The compositions outlined in the foregoing are not related to practicing said method, in for example, a mouse, or for that matter in another yeast species (e.g., *S. cerevisiae*).

Furthermore, none of the other methods comprise the same steps or components, thus this group does not share special technical feature with any of the other groups.

As between the groups directed to identification of the presence of *C. albicans* in a sample from a subject, the methods are distinguishable in that group 755 incorporates antibody identification technique, while group 756 incorporates nucleic acid hybridization technique. Each of said techniques inheres specialized steps and components that are not shared between the two groups (e.g., antibody versus nucleic acid, hybridization versus protein-protein binding, cross-reactivity, mismatch binding, visualization). Furthermore, none of the foregoing groups share the same components, elements or steps, which define the instant groups' special technical features.

For the reasons given above these inventions are distinct and have are directed to distinguishable special technical features. Applicant is advised that a reply to this restriction requirement must include an election for the invention (e.g., Group 1, 2 or 3, etc.) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanies by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

The claims encompass 756 distinct inventions, thus are subject to a restriction requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached between 8:30-5:00, Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 571-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636

GERRY LEFFERS
PRIMARY EXAMINER